proposal and noted in section II.C.3.c below, the Administrator has placed primary weight on the air-related IQ loss evidence-based framework in his decision with regard to level, and less weight on risk estimates from the quantitative risk assessment. At the same time, as stated in section II.C.3.c below, he finds those estimates to be roughly consistent with and generally supportive of the estimates from the evidence-based framework.

c. Conclusions on Level

Having carefully considered the public comments on the appropriate level of the Pb standard, as discussed above, the Administrator believes the fundamental scientific conclusions on the effects of Pb reached in the Criteria Document and Staff Paper, briefly summarized above in sections II.A.1 and II.A.2 and discussed more fully in sections II.A and II.B of the proposal, remain valid. In considering the level at which the primary Pb standard should be set, as in reaching a final decision on the need for revision of the current standard, the Administrator considers the entire body of evidence and information, in an integrated fashion, giving appropriate weight to each part of that body of evidence and information. In that context the Administrator continues to place primary consideration on the body of scientific evidence available in this review on the health effects associated with Pb exposure. In so doing, the Administrator primarily focuses on the air-related IQ loss evidence-based framework summarized in section II.C.3.a above and described in the proposal, recognizing that it provides useful guidance for making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary.

As described in section II.E.3.d of the proposal and recognized in section II.C.3.a above, the air-related IQ loss framework is used to inform the selection of a standard level that would protect against air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in subpopulations of children exposed to the level of the standard, taking into consideration uncertainties inherent in such estimates. This framework calls for identifying a target degree of protection in terms of an air-related IQ loss for such subpopulations of children (discussed further below), as well as two other parameters also relevant to this framework—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio.

With regard to estimates for air-to-blood ratio, the Administrator has further considered the evidence regarding air-to-blood relationships described in section II.A.2.a.iii above in light of advice from CASAC and comments from the public as described in section II.C.2.b above. Accordingly, he recognizes that the evidence includes support for ratios greater than 1:7 (the upper end of the range focused on in the proposal), including estimates ranging from 1:8 to 1:10. He also recognizes that the estimates developed from the quantitative exposure and risk assessments also include values greater than 1:7, including values ranging up to 1:10 and some higher. Additionally, as noted in section II.A.2.a.iii above, the evidence as a whole also indicates that variation in the value of the ratios appears to relate to the extent to which the range of air-related pathways are included and the magnitude of the air and blood Pb levels assessed, such that higher ratios appear to be associated with more complete assessments of air-related pathways and lower air and blood Pb levels. Taking all of these considerations into account, the Administrator concludes that the reasonable range of air-to-blood estimates to use in the air-related IQ loss framework includes ratios of 1:5 up to ratios on the order of 1:10. He does not consider lower ratios to be representative of the full range of air-related pathways and the ratios expected at today's air and blood Pb levels. The Administrator also concludes that it is appropriate to focus on 1:7 as a generally central value within this range.

With regard to C–R functions, the Administrator has further considered the evidence regarding quantitative relationships between IQ loss and blood Pb levels described in section II.A.2.c above, in light of advice from CASAC and comments from the public as described in section II.C.3.b above. He recognizes the evidence of nonlinearity and of steeper slopes at lower blood Pb levels (summarized in section II.A.2.c above), and as a result, he believes it is appropriate to focus on those analyses that are based on blood Pb levels that most closely reflect today's population of children in the U.S., recognizing that the evidence does not include analyses involving mean blood Pb levels as low as the mean blood Pb level for today's children. He notes that, as described in section II.C.3.b above, a review of the evidence with this focus in mind has identified four analyses that have a mean blood Pb level closest to today's mean for U.S. children and that yield four slopes ranging from −1.56 to −2.94, with a median of −1.75 IQ points per μg/dL (Table 3). The Administrator concludes that it is appropriate to consider this set of C–R functions for use in the air-related IQ loss evidence based framework, as this set of C–R functions best represents the evidence pertinent to children in the U.S. today. In addition, the Administrator determines that it is appropriate to give more weight to the central estimate for this set of functions, which is the median of the set of functions, and not to rely on any one function.

As noted in the proposal, in considering this evidence-based framework, the Administrator recognizes that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to protect against risk of neurocognitive effects in sensitive populations, such as IQ loss in children. With regard to making a public health policy judgment as to the appropriate protection against risk of air-related IQ loss and related effects, the Administrator believes that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognizes, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety.

The Administrator generally agrees with CASAC and the commenters who emphasize that the NAAQS should prevent air-related IQ loss of a significant magnitude in all but a small percentile of the population. However, as discussed above in section II.C.3.b, it is important to note that in selecting a target degree of public health protection that should be afforded to at-risk populations of children in terms of air-related IQ loss as estimated by the evidence-based framework being applied in this review, the Administrator is not determining a specific quantitative public health policy goal for air-related IQ loss that would be acceptable or unacceptable for the entire population of children in the United States. Instead, he is determining what magnitude of estimated air-related IQ loss should be used in conjunction with this specific framework, in light of the uncertainties in the framework and the limitations in using the framework.

In that context, the air-related IQ loss framework provides estimates for the mean air-related IQ loss of a subset of the population of U.S. children, and there are uncertainties associated with those estimates. It provides estimates for that subset of children likely to be exposed to the level of the standard, which is generally expected to be the subpopulation of children living near sources who are likely to be most highly exposed. In providing estimates of the mean air-related IQ loss for this subpopulation of children, the framework does not provide estimates of the mean air-related IQ loss for all U.S. children. The Administrator recognizes, as discussed above, that EPA is unable to quantify the percentile of the U.S. population of children that corresponds to the mean of this sensitive subpopulation, nor can EPA confidently develop quantified estimates for upper percentiles for this subpopulation. EPA expects that the mean of this subpopulation represents a high, but not quantifiable, percentile of the U.S. population of children. As a result, the Administrator expects that a standard based on consideration of this framework would provide the same or greater protection from estimated air-related IQ loss for a high, albeit unquantifiable, percentage of the entire population of U.S. children.[83]

In addition, EPA expects that the selection of a maximum, not to be exceeded, form in conjunction with a rolling 3-month averaging time over a three-year span, discussed in section II.C.2. above, will have the effect that the at-risk subpopulation of children will be exposed below the level of the standard most of the time. In light of this and the significant uncertainty in the relationship between time period of ambient level, exposure, and occurrence of a health effect, the choice of an air-related IQ loss to focus on in applying the framework should not be seen as a decision that a specific level of air-related IQ loss will occur in fact in areas where the revised standard is just met or that such a loss has been determined as acceptable if it were to occur. Instead, the choice of such an air-related IQ loss is one of the judgments that need to be made in using the evidence-based framework to provide useful guidance in making the public health policy judgment on the degree of protection from risk to public health that is sufficient but not more than necessary, taking into consideration the patterns of air quality that would likely occur upon just meeting the standard as revised in this rulemaking.

In considering the appropriate air-related IQ loss to accompany application of the framework, the Administrator has considered the advice of CASAC and public comments on this issue, discussed above in section II.C.3.b. The Administrator recognizes that comments on the proposal have highlighted the ambiguity in using an air-related IQ loss for the framework that is phrased in terms of a range. For example, if a range of 1–2 points IQ loss is selected, it is unclear whether the intent is to limit points of air-related IQ loss to below 1, below 2, or below some level in between. For clarity, it is more useful to use a specific level as compared to a range. In addition, recognizing the uncertainties inherent in evaluating the health impact of an IQ loss across a population, as well as the uncertainties in the inputs to the framework, the Administrator believes it is appropriate to use a whole number for the air-related IQ loss level.

In consideration of comments from CASAC and the public and in recognition of the uncertainties in the health effects evidence and related information, as well as the role of a selected air-related IQ loss in the application of the framework, the Administrator concludes that an air-related IQ loss of 2 points should be used in conjunction with the evidence-based framework in selecting an appropriate level for the standard. Given the uncertainties in the inputs to the framework, the uncertainties in the relationship between ambient levels, exposure period, and occurrence of health effects, and the focus of the framework on the sensitive subpopulation of more highly exposed children, a standard level selected using this air-related IQ loss, in combination with the selected averaging time and form, would significantly reduce and limit for a high percentage of U.S. children the risk of experiencing an air-related IQ loss of that magnitude.

With this specific air-related IQ loss in mind, the Administrator considered the application of this framework to a broad range of standard levels, using estimates for the two key parameters—air-to-blood ratio and C–R function—that are appropriate for use within the framework, as shown in Table 4 below. In so doing, the Administrator recognized that, relying on the median of the four C–R functions from analyses with blood Pb levels closest to those of today's children, a standard level in the lower half of the proposed range (0.10–0.20 $\mu g/m^3$) would limit the estimated mean IQ loss from air-related Pb to below 2 points, depending on the choice of air-to-blood ratio within the range from 1:5 to 1:10.

As noted above, however, the Administrator does not believe it is appropriate to consider only a single air-to-blood ratio. Using the air-to-blood ratio of 1:7, a generally central estimate within the well supported range of estimates, the estimates of air-related IQ loss are below a 2-point IQ loss for standard levels of 0.15 $\mu g/m^3$ and lower. At a level of 0.15 $\mu g/m^3$, the Administrator recognizes that use of a 1:10 ratio produces an estimate greater than 2 IQ points and use of a 1:5 ratio produces a lower IQ loss estimate. Given the uncertainties and limitations in the air-related IQ loss framework, the Administrator views it as appropriate to place primary weight on the results from this central estimate rather than estimates derived using air-to-blood-ratios either higher or lower than this ratio.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD

Potential level for standard ($\mu g/m^3$)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C–R functions with blood Pb levels closer to those of today's U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.50	>5 *	>5 *	4.4 (3.9–7.4)

[83] Further, in determining what level of estimated IQ loss should be used for evaluating the results obtained from this specific evidence-based framework, the Administrator is not determining that such an IQ loss is appropriate for use in other contexts.

TABLE 4—ESTIMATES OF AIR-RELATED MEAN IQ LOSS FOR THE SUBPOPULATION OF CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD—Continued

Potential level for standard ($\mu g/m^3$)	Air-related mean IQ loss (points) for the subpopulation of children exposed at level of the standard		
	IQ loss estimate is based on median slope of 4 C–R functions with blood Pb levels closer to those of today's U.S. children (range shown for estimates based on lowest and highest of 4 slopes)		
	Air-to-blood ratio		
	1:10	1:7	1:5
0.40		4.9 (4.4–8.2)	3.5 (3.1–5.9)
0.30	5.3 (4.7–8.8)	3.7 (3.3–6.2)	2.6 (2.3–4.4)
0.25	4.4 (3.9–7.4)	3.1 (2.7–5.1)	2.2 (2.0–3.7)
0.20	3.5 (3.1–5.9)	2.5 (2.2–4.1)	1.8 (1.6–2.9)
0.15	2.6 (2.3–4.4)	1.8 (1.6–3.1)	1.3 (1.2–2.2)
0.10	1.8 (1.6–2.9)	1.2 (1.1–2.1)	0.9 (0.8–1.5)
0.05	0.9 (0.8–1.5)	0.6 (0.5–1.0)	0.4 (0.4–0.7)
0.02	0.4 (0.3–0.6)	0.2 (0.2–0.4)	0.2 (0.2–0.3)

* For these combinations of standard levels and air-to-blood ratios, the appropriateness of the C–R function applied in this table becomes increasingly uncertain such that no greater precision than ">5" for the IQ loss estimate is warranted.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of risk of air-related IQ loss. The Administrator finds that these quantitative assessments provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as summarized in section II.A.3 above and discussed in sections II.C and II.E.3.b of the proposal, for purposes of evaluating potential standard levels, the Administrator places less weight on the risk estimates than on the evidence-based assessment. Nonetheless, the Administrator finds that the risk estimates are roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates summarized above.[84]

In the Administrator's view, the above considerations, taken together, provide no evidence-or risk-based bright line that indicates a single appropriate level. Instead, there is a collection of scientific evidence and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making the public health policy judgment to select the appropriate standard level from a range of reasonable values. In addition, the results of the evidence-based framework are seen as a useful guide in determining whether the risks to public health from exposure to ambient levels of Pb in the air, in the context of a specified averaging time and form, provide a degree of protection from risk with an adequate margin of safety that is sufficient but not more than necessary.

Based on consideration of the entire body of evidence and information available at this time, as well as the recommendations of CASAC and public comments, the Administrator has decided that a level for the primary Pb standard of 0.15 $\mu g/m^3$, in combination with the specified choice of indicator, averaging time, and form, is requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. The Administrator notes that this level is within the range recommended by CASAC, the Staff Paper, and by the vast majority of commenters. The Administrator concludes that a standard with a level of 0.15 $\mu g/m^3$ will reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and the potential for cardiovascular and renal effects in adults.

The Administrator notes that the evidence-based framework indicates that for standard levels above 0.15 $\mu g/m^3$, the estimated mean air-related IQ loss in the subpopulation of children exposed at the level of the standard would range in almost all cases from above 2 points to 5 points or more with the range of air-to-blood ratios considered. He concludes, in light of his consideration of all of the evidence, including the framework discussed above, that the protection from air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.15 $\mu g/m^3$ would not be sufficient to protect public health with an adequate margin of safety.

In addition, the Administrator notes that for standard levels below 0.15 $\mu g/m^3$, the estimated mean IQ loss from air-related Pb in the subpopulation of children exposed at the level of the standard would generally be somewhat to well below 2 IQ points regardless of which air-to-blood ratio within the range of ratios considered was used. The Administrator concludes in light of all of the evidence, including the evidence-based framework, that the degree of public health protection that standards below 0.15 $\mu g/m^3$ would likely afford would be greater than what is necessary to protect public health with an adequate margin of safety.

The Administrator also recognizes that several commenters expressed concern that the proposal did not adequately address the need for the standard to be set with an adequate margin of safety. As noted above, in section I, the requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in

[84] For example, in considering a standard level of 0.2 $\mu g/m^3$, we note that the risk assessment provides estimates falling within the range of 1.2 to 3.2 points IQ loss for the general urban case study and <3.7 for the primary Pb smelter subarea. These estimates are inclusive of the range of estimates for the 0.20 standard level presented in Table 4 based on the median C–R slope applied in the air-related IQ loss framework. As noted in section II.A.3.a above, these case studies, based on the nature of the population exposures represented by them, relate more closely to the air-related IQ loss evidence-based framework than other case studies assessed.

selecting a primary standard that includes an adequate margin of safety, the Administrator is seeking not only to prevent pollutant levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

Nothing in the Clean Air Act, however, requires the Administrator to identify a primary standard that would be protective against demonstrated harms, and then identify an additional "margin of safety" which results in further lowering of the standard. Rather, the Administrator's past practice has been to take margin of safety considerations into account in making decisions about setting the primary standard, including in determining its level, averaging time, form and indicator, recognizing that protection with an adequate margin of safety needs to be sufficient but not more than necessary.

Consistent with past practice, the Administrator has taken the need to provide for an adequate margin of safety into account as an integral part of his decision-making on the appropriate level, averaging time, form, and indicator of the standard. As discussed above, the consideration of health effects caused by different ambient air concentrations of Pb is extremely complex and necessarily involves judgments about uncertainties with regard to the relationships between air concentrations, exposures, and health effects. In light of these uncertainties, the Administrator has taken into account the need for an adequate margin of safety in making decisions on each of the elements of the standards. Consideration of the need for an adequate margin of safety is reflected in the following elements: selection of TSP as the indicator and the rejection of the use of PM_{10} scaling factors; selection of a maximum, not to be exceeded form, in conjunction with a 3-month averaging time that employs a rolling average, with the requirement that each month in the 3-month period be weighted equally (rather than being averaged by individual data) and that a 3-year span be used for comparison to the standard; and, the use of a range of inputs for the evidence-based framework, that includes a focus on higher air-to-blood ratios than the lowest ratio considered to be supportable, and steeper rather than shallower C-R functions, and the consideration of these inputs in selection of 0.15 $\mu g/m^3$ as the level of the standard. The Administrator concludes based on his review of all of the evidence (including the evidence-based framework) that when taken as a whole the standard selected today, including the indicator, averaging time, form, and level, will be sufficient but not more than necessary to protect public health, including the health of sensitive subpopulations, with an adequate margin of safety.

Thus, after carefully taking the above comments and considerations into account, and fully considering the scientific and policy views of the CASAC, the Administrator has decided to revise the level of the primary Pb standard to 0.15 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level and using the specified indicator, averaging time, and form would be requisite to protect public health with an adequate margin of safety. The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral and neurocognitive effects, in children. A standard set at this level provides a very significant increase in protection compared to the current standard. The Administrator believes that a standard set at 0.15 $\mu g/m^3$ would be sufficient to protect public health with an adequate margin of safety, and believes that a lower standard would be more than what is necessary to provide this degree of protection. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

D. Final Decision on the Primary Lead Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and the public comments, the Administrator is revising the various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, including neurocognitive and neurobehavioral effects. Specifically, the Administrator has decided to revise the level of the primary standard to a level of 0.15 $\mu g/m^3$, in conjunction with retaining the current indicator of Pb-TSP. The Administrator has also decided to revise the form and averaging time of the standard to a maximum (not to be exceeded) rolling 3-month average evaluated over a 3-year period.

Corresponding revisions to data handling conventions, including allowance for the use of Pb-PM_{10} data in certain circumstances, and the treatment of exceptional events are specified in revisions to Appendix R, as discussed in section IV below. Corresponding revisions to aspects of the ambient air monitoring and reporting requirements for Pb are discussed in section V below, including sampling and analysis methods (e.g., a new Federal reference method for monitoring Pb in PM_{10}, quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

III. Secondary Lead Standard

A. Introduction

The NAAQS provisions of the Act require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that secondary standards be set to eliminate all risk of adverse welfare effects, but rather at a level requisite to protect public welfare from those effects that are judged by the Administrator to be adverse.

This section presents the rationale for the Administrator's final decision to revise the existing secondary NAAQS. In considering the currently available evidence on Pb-related welfare effects, there is much information linking Pb to potentially adverse effects on organisms and ecosystems. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient Pb, the Administrator concludes that the available evidence supports revising the secondary standard but does not provide a sufficient basis for establishing a secondary standard for Pb that is different from the primary standard.